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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,009	01/25/2001	Steven P. Holzberg	00801.0172.00US00	6352

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EXAMINER

HELMER, GEORGIA L

ART UNIT PAPER NUMBER

1638

DATE MAILED: 10/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/771,009

Applicant(s)

Holzberg et al.

Examiner

Phuong Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-67 are subject to restriction and/or election requirement

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-30 and 58, drawn to a polynucleotide encoding a promoter operatively linked to a transcriptional unit, classified in class 536, subclass 23.4.
 - II. Claims 31-43, drawn to a viral genome encoding a fusion protein, classified in class 536, subclass 23.72.
 - III. Claim 44, drawn to a viral genome with a mutation in the coat protein gene, classified in class 536, subclass 23.72.
 - IV. Claim 45, drawn to a method of expressing a protein of interest, classified in class 435, subclass 235.
 - V. Claim 46, drawn to a viral genome encoding a fusion protein and having a mutation in the coat protein gene, classified in class 536, subclass 23.72.
 - VI. Claims 47-55, drawn to a viral genome with a duplicated genomic nucleic acid component, classified in class 536, subclass 23.72.
 - VII. Claims 56-57, drawn to a method of expressing a protein of interest, classified in class 435, subclass 69.1.

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- VIII. Claim 59, drawn to a viral genome encoding a fusion protein and having a duplicated genomic nucleic acid component, classified in class 536, subclass 23.72.
- IX. Claims 60-61, drawn to a polynucleotide encoding a promoter operatively linked to a transcriptional unit, wherein the targeting sequence is substantially homologous to a gene of interest, classified in class 536, subclass 23.1.
- X. Claim 62, drawn to a method of decreasing expression of a peptide, classified in class 435, subclass 5.
- XI.. Claim 63, drawn to a method for causing a phenotypic or biochemical change in a plant host with a targeting sequence in sense orientation, classified in class 435, subclass 69.1.
- XII. Claim 63, drawn to a method for causing a phenotypic or biochemical change in a plant host with a targeting sequence in antisense orientation, classified in class 435, subclass 69.1.
- XIII. Claim 64, drawn to a method for correlating a nucleotide sequence with its function wherein the sequence is in sense orientation, classified in class 435, subclass 6.
- XIV. Claim 64, drawn to a method for correlating a nucleotide sequence with its function wherein the sequence is in antisense orientation, classified in class 435, subclass 6.

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- XV. Claim 65, drawn to a viral genome with a targeting sequence substantially homologous to a gene of interest and with a mutation in the coat protein gene, classified in class 536, subclass 23.72.
- XVI. Claim 66, drawn to a viral genome with a duplicated genomic nucleic acid component and a targeting sequence substantially homologous to a gene of interest, classified in class 536, subclass 23.72.
- XVII. Claim 67, drawn to a viral genome with a duplicated genomic nucleic acid component, a targeting sequence substantially homologous to a gene of interest, and a mutation in the coat protein gene, classified in class 536, subclass 23.72.

For each of invention I above, restriction to one of the following is also required under 35 USC

121. Therefore, if invention I is elected, then election is also required of one of inventions (A)-

(I).

- (A) SEQ ID NO:1
- (B) SEQ ID NO:2
- (C) SEQ ID NO:3
- (D) SEQ ID NO:4
- (E) SEQ ID NO:5
- (F) SEQ ID NO:6
- (G) SEQ ID NO:7
- (H) SEQ ID NO:8

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(I) SEQ ID NO:9

2. The inventions are distinct, each from the other because of the following reasons:

Inventions II, V and VIII, and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because each of the recited combinations is itself a combination of the subcombination of Group I and one of the subcombinations recited as Groups III and VI. Accordingly, each combination does not necessarily rely solely upon any one subcombination for its own patentability. The subcombination has separate utility as evidenced by the various combinations claimed as Groups II, V and VIII.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions V, XIV, and XVII, and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because each of the recited combinations is itself a combination of the subcombination of Group II and one of the subcombinations recited as Groups I, VI, and IX. Accordingly, each

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combination does not necessarily rely solely upon any one subcombination for its own patentability. The subcombination has separate utility as evidenced by the various combinations claimed as Groups V, XIV, and XVII.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions II, VIII, and XVI, and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because each of the recited combinations is itself a combination of the subcombination of Group VI and one of the subcombinations recited as Groups I, III and IX. Accordingly, each combination does not necessarily rely solely upon any one subcombination for its own patentability. The subcombination has separate utility as evidenced by the various combinations claimed as Groups II, V and VIII.

5. The inventions are distinct, each from the other because of the following reasons:

Inventions XIV, XVI, and XVII, and IX are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as

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claimed because each of the recited combinations is itself a combination of the subcombination of Group IX and one of the subcombinations recited as Groups III and VI. Accordingly, each combination does not necessarily rely solely upon any one subcombination for its own patentability. The subcombination has separate utility as evidenced by the various combinations claimed as Groups XIV, XVI, and XVII.

6. Inventions I, III, VI and IX are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the subcombinations have separate utility as evidenced by the various combinations II, IV, VIII, XIV, XV, XVI, and XVII. See MPEP § 806.05(d).

7. Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product can be used in another and materially different process such as one in which the viral genome is replicated in the host cell.

8. Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §

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806.05(h)). In the instant case, the product as claimed can be used in another and materially different process such as one in which the viral genome is replicated in the host.

9. Inventions IX and XI-XIV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, product as claimed can be used in another and materially different method as evidenced by the various methods of Groups XI-XIV.

10. Inventions (A)-(I) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions represent structurally different polynucleotides having different effects, in that each encodes a different autoproteolytic peptide linker. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

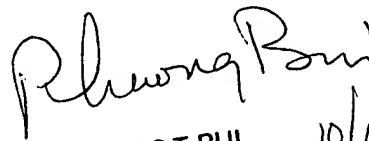
14. Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia Helmer whose telephone number is (703) 308-7023.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Georgia Helmer
Examiner
Group Art Unit 1638
September 30, 2002


PHUONG T. BUI
PRIMARY EXAMINER 10/1/02